

Appl. No. : 10/001684  
Filed : October 25, 2001

### REMARKS

Applicant acknowledges receipt of the Office Action mailed July 30, 2002 (Paper No. 5). To summarize, the PTO objected to the specification for alleged informalities. Additionally, the PTO rejected Claims 1-15 under 35 U.S.C. §112, first paragraph for failure to enable the treatment of polycystic ovary syndrome. Claim 2 was rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite. Claims 1-8 and 10-15 were rejected under 35 U.S.C. §102(e) as being anticipated by de la Harpe et al. (U.S. Patent No. 5,980,905).

Claims 1-15 are pending in the application; Claim 1 has been amended to recite a method of reducing symptoms associated with Polycystic Ovary Syndrome (PCOS). Support for the amendment is provided in the original claims as filed and throughout the specification. Reconsideration and withdrawal of the present rejections in view of the amendments and comments presented herein are respectfully requested.

The specific changes to the amended claim are shown on a separate page attached hereto and entitled VERSION WITH MARKINGS TO SHOW CHANGES MADE, which follows the signature page of this Amendment. On this page, the insertions are underlined while the [deletions are placed in brackets].

#### Regarding the Specification

The Patent and Trademark Office ("PTO") objected to the specification because it contained numerical references before each paragraph. Applicant respectfully submits that the numbering of paragraphs of the specification is prescribed by law. 37 C.F.R. §1.52(b)(6) states in relevant part:

Other than in a reissue application or reexamination proceeding, the paragraphs of the specification, other than in the claims or abstract, may be numbered at the time the application is filed, and should be individually and consecutively numbered using Arabic numerals, so as to unambiguously identify each paragraph.

(Emphasis added). Applicant is in full compliance with 37 C.F.R. §1.52(b)(6). Accordingly, withdrawal of the objection to the specification is respectfully requested.

#### Claims 1-15 are fully enabled by the specification

Claims 1-15 were rejected under 35 U.S.C. §112, first paragraph because, according to the PTO, the specification, while being enabling for a treatment for normalizing glucose levels,

does not reasonably provide enablement for a treatment for Polycystic Ovary Syndrome (PCOS). Applicant respectfully disagrees.

The PTO argues that because PCOS encompasses many secondary disease parameters, it would be difficult to treat and therefore alleged 'treatments' for PCOS are deemed unpredictable in the absence of evidence to the contrary. See Office Action (Paper No. 5), page 5. However, this general allegation is not backed up with any scientific reasoning specific to the presently claimed methods. What the PTO is arguing, in essence, is that claims to "treatment" of a disease are unlikely to be operable, and thus all treatment claims are unbelievable. However, this is simply not the standard of 35 USC §112. If the PTO disputes the operability of a claimed invention, it must back up that position with sound scientific reasoning or citations. No reasoning (except general allegations) has been presented here. Thus, the PTO fails to make a *prima facie* case of lack of enablement.

In this particular case, the Applicant clearly spells out the sound scientific basis for the invention. At pages 1-5 of the specification of the instant application, Applicant describes PCOS and the various conditions associated with the disease. In PCOS, an abnormality occurs in how the insulin receptor transmits signals. See paragraph [0013] of the specification. Accordingly, the hallmark features of PCOS include, *inter alia*, obesity, insulin resistance, and abnormal lipid profile. The present invention is based, in part, on the discovery that insulin insensitivity can play a significant role in the development of the various conditions associated with PCOS. For example, insulin resistance has been connected with hyperandrogenism. See paragraphs [0012] and [0020] of the specification. By improving insulin sensitivity in an individual suffering from PCOS, symptoms associated with the disease will be reduced. This discussion in the specification is logical and consistent with scientific principles. The PTO has not adduced any evidence contrary to this scientific discussion, and thus has made no *prima facie* case of nonenablement.

The citations to the *Wands* factors are not persuasive here. This is not a situation where the specification fails to disclose all the steps necessary to practice the invention, leaving the public to engage in experimentation. Instead, the specification clearly sets forth dosages, compositions, and routes of administration, all of which are straightforward. The PTO has failed to show what *any* experimentation would be required, let alone "undue experimentation."

The undersigned is aware that certain types of claims, e.g., those requiring a "cure," can require a higher degree of proof of operability. In this particular situation, Applicant is not claiming to cure polycystic ovary disease. Instead, the method is simply a treatment. However, to remove all doubt as to whether proof of a cure is required, Claim 1 has been amended to recite a method of reducing symptoms associated with PCOS. It is submitted that there are no *bona fide* enablement issues surrounding this language.

Applicant has observed that the administration of trivalent forms of chromium reduces the symptoms associated with PCOS by lowering blood glucose levels. In paragraph [0042] of the specification, Applicant identifies a variety of chromium complexes which can be administered to reduce the symptoms associated with PCOS. In paragraphs [0047] through [0057], Applicant describes the various ways in which the chromium complex can be formulated to achieve the reduction in symptoms associated with PCOS. Paragraph [0058] sets forth the prescribed dosage ranges of chromium for achieving the reduction of symptoms associated with PCOS. Furthermore, the Example details the administration of a chromium complex for the reduction of symptoms associated with PCOS such as obesity, insulin insensitivity, and abnormal lipid profiles.

In view of the disclosure discussed above, Applicant submits that one of ordinary skill in the relevant art would be able to practice the disclosed invention with the claimed chromium complexes to achieve a reduction in the symptoms associated with PCOS without undue experimentation. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph is therefore requested.

**Claim 2 is definite under 35 U.S.C. §112, second paragraph**

Claim 2 was rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The PTO opined that the term "chromium yeasts" was unclear. In response, we have conducted an internet search using the Google search engine for the exact term "chromium yeast." That search turned up 980 hits. A review of the first page of results (attached here as Exhibit A) shows that 7 of the 8 entries use "chromium yeast" as a term of art, and the other entry is an accidental hit in a PDF document. It is believed that this evidence should satisfy any concerns that the PTO has, and withdrawal of the rejection is respectfully requested.

**Claims 1-8 and 10-15 are not anticipated**

The PTO rejected Claims 1-8 and 10-15 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,980,905 ('905). Under 35 U.S.C. §102(e), a claim is anticipated only if the reference teaches each and every limitation of the claim. See Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir., 1987); M.P.E.P. §2131. Each element as set forth in the Claims 1-8 and 10-15 is not found in the '905 patent. Accordingly, Applicant respectfully submits that Claims 1-8 and 10-15 are not anticipated by '905 and request withdrawal of the PTO's rejection under 35 U.S.C. §102(b).

Review of '905 reveals that it discloses a composition for supplementing dietary chromium and facilitating absorption of essential metals comprising chromic polynicotinate in combination with at least one of a cyclooxygenase inhibitor, an acid, a mucolytic, and a salicin-containing herb. The claims of the present application, by contrast, recite a method for reducing the symptoms associated with PCOS. '905 neither discloses nor suggests the administration of a chromium complex alone to reduce the symptoms associated with PCOS, as claimed in Claim 1. In fact, the reference is completely silent with respect to PCOS. Because the present claims recite methods of reducing the symptoms associated with PCOS and because '905 fails to teach the administration of a chromium complex for reducing PCOS symptoms, '905 fails to teach each and every limitation of the claims. Accordingly, '905 does not anticipate claims 1-8 and 10-15.

We note that the PTO did not search the claimed invention, but instead reviewed what it believed was enabled by the specification. This approach is contrary to well-established law, which requires the PTO to give weight to all claim limitations, including (in the present case) selection of the patient population to which the treatment is administered. In this case, the claim requires selection of a particular patient population that is not targeted or mentioned in the reference.

**CONCLUSION**

In view of the foregoing remarks, Applicant respectfully submits that the present application is in condition for allowance. Nevertheless, the PTO is invited to contact the undersigned at the telephone number appearing below to discuss any remaining issues. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to

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otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: October 25, 2001

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS**

Claim 1 was amended as follows:

1. (AMENDED) A method of reducing symptoms associated with [treating] Polycystic Ovary Syndrome (PCOS) comprising:
  - identifying a subject suffering from PCOS; and
  - administering to said subject an effective dose of a composition comprising at least one chromium complex.